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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Application Number: 09/744,866

Filing Date: April 02, 2001

Appellant(s): AUSTRUP ET AL.

Eric S. Spector

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 7, 2005, appealing from the Office action mailed June 9, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because for the following reasons:

Appellant has stated the claims are directed to isolating disseminated tumor cells by screening body fluid, where the disseminated tumor cells are not modified prior to screening. "Screening" is a term of art, which has been misused in Appellant's characterization of the claimed subject matter. In the relevant art of medicine, and more particularly clinical diagnostics, the term "screening" is ordinarily given the meaning that is provided, for example, by The On-line Medical Dictionary (published at the Centre for Cancer Education, University of

Newcastle upon Tyne), which is available on the Internet at http://cancerweb.ncl.ac.uk/omd/.

The On-line Medical Dictionary defines the term "screening" as "[e]xamination of people with no symptoms, to detect unsuspected disease" (© Copyright 1997-2005 -The CancerWEB Project).

Contrasting this definition, the claims are drawn to a process for isolating disseminated tumor cells from a bodily fluid, said process comprising *passing the fluid or part thereof through a screen* such that disseminated tumor cells, which were contained in the fluid, are retained on the screen. Accordingly, it is submitted that Appellant's summary of the claimed subject matter is deficient. Therefore, a correct summary of the claimed subject matter for clear understanding of the claimed invention follows:

> The claims are directed to a process for isolating disseminated tumor cells from a bodily fluid, said process comprising passing the fluid or part thereof through a screen such that disseminated tumor cells, which were contained in the fluid, are retained on the screen, wherein the disseminated tumor cells are not modified prior to screening (i.e., passing the fluid through the screen) by any of the following: (a) labeling; (b) attaching particles; (c) triggering aggregation or cluster formation; (d) with

antibodies; (e) enzymes; (f) lectins; (g) other ligands; (h) other receptors; (i) cross linking agents; and (j) fixing.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct; however, it is aptly noted that Appellant has stated the claims are rejected under 35 U.S.C. § 112, first paragraph, "particularly on the basis that the inventors did not have in mind at the time the application was filed, carrying out the screening of claims 24 and 28 with unmodified disseminated tumor cells". While the claims are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, the particular reason cannot be that "the inventors did not have in mind at the time the application was in filed, carrying out [the claimed processes]", since it is not possible to ascertain what was in the mind of the inventors. Rather the particular reason that the claims are rejected, as failing to satisfy the written description provision, is that *the disclosure* would not reasonably convey to the skilled artisan that Appellant had possession of the claimed invention at the time the application was filed, since it does not adequately describe a process as now claimed.

Accordingly, the changes, which are made to the grounds of rejection, are as follows:

> Claims 24 and 28 are drawn a process for isolating disseminated tumor cells from a bodily fluid, said process comprising passing the fluid or part thereof through a screen such that disseminated tumor cells, which were contained in the fluid, are retained on the screen, wherein the disseminated tumor cells are not modified prior to screening (i.e., passing the fluid through the screen), but more particularly, wherein the disseminated tumor cells are not modified by any one of following: (a) labeling; (b) attaching particles; (c) triggering aggregation or cluster formation; (d) with antibodies; (e) enzymes; (f) lectins; (g) other ligands; (h) other receptors; (i) cross linking agents; and (j) fixing.

It is recognized that the recitation that the disseminated tumor cells are not so modified prior to passing the fluid through the screen is a negative limitation that excludes the prior art of record from serving as anticipatory of the disclosed, but not now claimed, subject matter under 35 U.S.C. §§ 102 and/or 103.

Appellant has asserted that written support for recitation of this negative limitation in claims 24 and 28 is found in the specification. For example, in the amendment filed January 18, 2005, first incorporating this negative limitation, it was asserted that the specification, including the claims, as originally filed, provides such necessary written support at page 13, lines 25-32.

As explained at section 11 beginning at page 11 of the FINAL Office action mailed June 9, 2005, contrary to Appellant's assertion, the originally filed specification does not appear to provide proper and sufficient written support for the recitation of this negative limitation. Any claim containing a negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The disclosure to which Appellant referred at page 13 of the specification *positively* recites the inclusion of a step comprising modifying the tumor cells before passing a suspension of the cells through a screen. However, the mere presence of a positive recitation is not basis for exclusion. Any negative limitation or exclusionary proviso must have basis *in the original disclosure*. The disclosure, as originally filed, does not provide the necessary support for the recitation of this negative limitation in the claims, because the disclosure does not teach the exclusion of a step in which the tumor cells are modified (e.g., by attaching the cells to particles comprising an antibody) before passing a suspension of the cells through the screen). While at page 19 the disclosure teaches the cancer cells are successfully provided as isolates from bodily fluids, which are free from the separating agent used, e.g., a particle comprising an antibody, this disclosure does not teach the exclusion of a step comprising attaching a particle comprising an antibody to the cells before passing the sample through a screen. Furthermore, while at pages 5 and 6 the specification teaches some limitations associated with the antigen-specific

immunoadsorption-based methods, at page 13 the specification clearly teaches the invention can comprise modifying the cancer cells by attaching particles comprising antibodies prior to the step of screening.

Adding the expressed exclusion of certain elements implies permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations, in fact, introduce new concepts. See *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983). Furthermore, Appellant is reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972).

As further noted in the FINAL Office action mailed June 9, 2005, in the amendment filed January 18, 2005, Appellant referred to various case law, including the decision rendered by the Court in deciding *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187 (CCPA 1977). The response indicated, MPEP § 2173.05(i) states on the basis of such case law, including *In re Johnson:* "Any negative limitation or exclusionary proviso must have basis **in the original disclosure**" (emphasis added). In deciding *In re Johnson*, the Court indicated that since appellant had described the genus *and* the species, which appellant had deliberately excluded from the claimed subject matter by the proviso exclusion of those species, appellant had not created "an artificial genus" (or an

inadequately described subgenus), because the specification, having described the whole, must necessarily have described the part remaining after the proviso exclusion of the species. In this instance, however, Appellant's original disclosure does not include a description of the species Appellant wishes to exclude. In deciding *Ex parte Grasselli*, the Board indicated that such an attempt to exclude species of a genus, which had not been described, introduces new matter into the specification as originally filed. See also *In re Welstead*, 174 USPQ 449 (CCPA 1972); and *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971). See MPEP § 2163.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

M.P.E.P. §§ 2163 and 2173.05(i).

Ex parte Grasselli, 231 USPQ 393 (BPAI 1983).

In re Smith, 173 USPQ 679, 683 (CCPA 1972).

In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187 (CCPA 1977).

In re Welstead, 174 USPQ 449 (CCPA 1972).

In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971).

University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

The Reagents of the University of California v. Eli Lilly, 43 USPQ2d 1398 (CAFC 1997).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The particular reasons that claims 24 and 28 are rejected, as failing to comply with the written description requirement, have already been addressed above in section 6 of this Examiner's Answer, correcting Appellant's statement of the grounds of rejection to be reviewed on appeal.

In addition to those grounds of rejection previously presented, it is herein noted that, at page 13, lines 25-32, the specification discloses (with particular emphasis added) the following:

> Furthermore it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation **and/or** cluster formation **using**, for example, suitable antibodies, enzymes, lectins, other ligands **and/or** receptors **or** crosslinking reagents, by fixing and by inducing other defined states.

There are noteworthy differences between the negative limitation recited in claims 24 and 28 and this disclosure, which is asserted by Appellant to provide written support for the recitation in the claims.

Therefore, *arguendo*, were the disclosure at page 13, lines 25-32, decidedly sufficient to provide support for a recitation of a negative limitation requiring the disseminated tumor cells not be modified prior to passing the fluid through the screen, it is submitted that *at best*, the disclosure would provide support for the following limitation: "wherein the disseminated tumor cells (i.e., cancer cells) in said cell-containing body fluid (i.e., the cell suspension) are not modified prior to passing the fluid through the screen by (a) labeling; (b) attaching particles; (c) triggering aggregation and/or cluster formation using antibodies, enzymes, lectins, ligands, and/or receptors; (d) triggering aggregation and/or cluster

formation using crosslinking reagents; (e) fixing; and (f) inducing other defined states".

It is submitted that as the disclosure at page 13, lines 25-32, is the disclosure that Appellant has asserted provides the necessary written support, the "reengineering" of this disclosure to *create* the notably different negative limitation now recited in claims 24 and 28 constitutes a violation of the written description provision set forth under 35 U.S.C. § 112, first paragraph. For example, claims 24 and 28 require the disseminated tumor cells not be modified by antibody, whereas the disclosure more particularly describes modifying cancer cells in the cell suspension by triggering aggregation and/or cluster formation *using* antibodies. It is most possible to modify a tumor cell by means of an antibody without triggering aggregation and/or cluster formation. Accordingly, was the positive recitation decidedly sufficient basis for a recitation of a proviso that the disseminated tumor cells are not modified prior to passing the fluid through the screen, it is submitted that the disclosure at page 13, lines 25-32, would not be sufficient to support a claim requiring the disseminated tumor cells not be modified to *any extent* by any of the specific means now recited in the present claims, such as antibodies. Rather the disclosure would merely provide support for, as an example, a proviso that the disseminated tumor cells are not modified prior to passing the fluid through the screen by triggering aggregation

and/or cluster formation using antibodies, enzymes, lectins, ligands, and/or receptors.

It is further submitted that as the disclosure at page 13, lines 25-32, is the only substantially literal basis for the negative limitation now recited in the claims, it is a violation of the written description provision not to include in that recitation the further *alternative* proviso that the disseminated tumor cells are not modified "by inducing other defined states", which is included in the disclosed positive statement at lines 31 and 32. Appellant has no basis for choosing only select means of modifying disseminated tumor cells from those disclosed, and eliminating others, where the positive statement is allegedly the basis for the negative limitation of claims 24 and 28.

(10) Response to Argument

Appellant has contended the positive statement, which is disclosed at page 13, lines 25-32, of the specification shows the inventors had possession of the claimed invention at the time the application was filed, as claims 24 and 28 "track wording quoted above [i.e., the disclosure at page 13, lines 25-32] but indicate that the modifications described are not present" (Brief, page 4, paragraph 2). Appellant has stated that hence the disclosure at page 13, lines 25-32, indicates Appellant had in mind at the time the application was filed two scenarios:

(1) A scenario in which the cancer cells are not modified in the cell suspension (i.e., the cell-containing bodily fluid) prior to passing the fluid through the screen "by labeling, by attaching particles, by triggering aggregation and/or cluster formation using antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagent or by fixing" (Brief, page 4, paragraph 3); and

(2) A scenario in which the cancer cells are so modified in the cell suspension prior to passing the fluid through the screen.

Because the disclosure at page 13, lines 25-32, teaches it is "also possible" to modify the cancer cells, although not expressly teaching the exclusion of such a modification step, Appellant has argued the skilled artisan would be "compelled" to interpret the disclosure as indicating possession of the subject matter now claimed. Appellant has further argued, it seems the Office is taking the position that the written description provision has not been met on the basis that the provisionary, or negative limitation recited in claims 24 and 28 is not explicitly set forth in the application, as filed, and that is not the test.

In response, Appellant is indeed correct, the invention need not be described *ipsis verbis* in the application, a filed, to satisfy the written description provision; however, it is aptly noted the Federal Circuit has recently explained that even *in*

ipsis verbis support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *The Reagents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 1406 (CAFC 1997).

See also: University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004). Although such decisions were made in relation to claims drawn to products, the statute applies to all types of inventions, whether products or processes, and the need to satisfy the requirement so provided by conveying to the skilled artisan that Appellant had possession of what is now claimed at the time the application was filed is no different. Satisfaction of this requirement in this instance is only met by establishing that the disclosure clearly and distinctly describes, whether implicitly, intrinsically, or expressly, a process for isolating disseminated tumor cells by passing a bodily fluid containing such tumor cells through a screen, such that the tumor cells are retained by that screen, which process does not require prior modification of the tumor cells contained in the bodily fluid by any of the specific means now recited in claims 24 and 28.

It is the position of the Office that the mere appearance of the positive statement that it is also possible to modify the cancer cells in the cell suspension prior to passing it through the screen by any of a variety of specifically recited means, including, for example, means such as broadly "inducing other defined states", does not imply possession of, or constitute a clear and distinct description of the processes now claimed, particularly as the claimed processes do not recite the alternative proviso that the tumor cells not be modified by inducing other defined states. As the disclosure at page 13, lines 25-32, is the only substantial basis, whether that basis is arguably literal or implied, for the negative limitation now recited in the claims, it is a violation of the written description provision not to include in that recitation the further *alternative* proviso that the disseminated tumor cells are not modified "by inducing other defined states", which is included in the disclosed positive statement at lines 31 and 32. Appellant has no basis for choosing only select means of modifying disseminated tumor cells from those disclosed, and eliminating others, where the positive statement is allegedly the basis for the negative limitation of claims 24 and 28.

Appellant has newly argued that the disclosure at page 25, lines 25-32, *together with* the working example at page 35 shows Appellant had possession of the claimed subject matter at the time the application was filed, since the example does not disclose the inclusion of a step of modifying the cancer cells prior to

passing a mononuclear cell-containing fraction of a suspension of cells isolated from samples of blood through a screen. As written, the alleged "working example" *of the claimed processes* appears a mere protocol for a process, which is prophetically used to isolate disseminated tumor cells; it does not appear a description of a process that was actually performed, which yielded isolated disseminated tumor cells. This position is supported by the use of verb tense; for example, the disclosure reads, 10 ml of heparinized blood **are** centrifuged"; the interface cells [...] **are** removed and washed"; and 9 ml of cell mixture **are** passed via a column through a 20 μm mesh screen" (emphasis added). Then, only as "an alternative", does the specification disclose at beginning at page 35, line 36, "the screen **may** be removed from the column, turned over and transferred into PBS [...], and the cells **may** be pelleted by centrifugation" (emphasis added). As such, it is not immediately apparent that Example 1 constitutes exemplification of the actual use of the claimed invention to isolate disseminated tumor cells by a process comprising passing a cell-containing bodily fluid or part thereof through a screen without prior modification of the cancer cells by any of the means now specifically recited in the claims, as opposed to guidance as how fractions of blood or other bodily fluids, which may contain disseminated tumor cells, may be prepared and processed through a screen, though not necessarily with or without prior modification by any of the specific means recited in claims 24 and 28. Again, to satisfy the written description requirement, the disclosure should describe the subject matter that is

now claimed in such a clear and distinct manner that it would immediately convey to the skilled artisan that Appellant had possession of that subject matter at the time the application was filed. Example 2 at page 36 describes a process for use in isolating CD45+ cells that comprises modifying the cells by attaching an antibody conjugated to microbeads; and beginning at page 36, Example 3 describes a genetic analysis that is performed using cellular material retained on the screen, which is prepared according to Example 1, or using CD45+ cells, which are isolated according to Example 2. Example 4, which begins at page 39, appears to be a description of actual experimentation performed by Appellant prior to the filing date of the application, given the use of the past tense of verbs, and describes the acquisition of data, which is supposedly presented in tabulated form in Tables I and II, but neither of which is found in the specification, as filed. Example 5 (pages 40 and 41), which also appears to be a description of actual experimentation performed by Appellant prior to the filing date of the application, describes the isolation of disseminated tumor cells, but notably in each instance by a process according to Example 2, not a process according to Example 1 (page 40, lines 37 and 38; and page 41, lines 17 and 18). Again, Example 2 teaches a process for isolating cells by modifying the cells with an antibody conjugated to microbeads. Accordingly, the disclosure does not describe the subject matter that is now claimed in such a clear and distinct manner, so as to immediately convey to the skilled artisan that Appellant had possession of that subject matter at the time the application was filed.

Even if Example 1 were decidedly to provide working exemplification (prophetic or actual) of a process for isolating disseminated tumor cells, *at best* the disclosure would merely provide written support for a process comprising passing a cell-containing bodily fluid or part thereof through a screen, though not necessarily before modification of the cancer cells, or moreover not necessarily prior to modification *by any of the means now specifically recited in the claims*.

Finally at page 6 of the Brief Appellant has argued that the claimed process provides pure, preserved, and unmodified disseminated tumor cells, which are not modified by means, including "inducing other defined states", which would not preserve their original state. Here, notably, Appellant has argued that the claimed process yields disseminated that were not modified by "inducing other defined states" prior to passing the fluid through the screen, but claims 24 and 28 do not recite such a proviso. As explained, although Appellant has no apparent basis for choosing only select means of modifying disseminated tumor cells from those disclosed, and eliminating others, where the positive statement is allegedly the basis for the negative limitation of claims 24 and 28, it is curious that Appellant now argues the claimed process yields such tumor cells unaltered by any means of modification inducing "other defined states", particularly since the specification teaches at least in one instance the isolated disseminated tumor cells were not able to proliferate (page 41, lines 11 and 12). Disseminated tumor

cells isolated by the exemplified process, which are not able to proliferate, cannot reasonably be said to have remained unaltered from their original state. Nevertheless, if indeed possible to isolate unaltered disseminated tumor cells by the processes described in the specification, given the disclosures of the prior art of record, it is evident that it is not inherently a property of the claimed process *alone* that yields isolated disseminated tumor cells, which are substantially unaltered from their original state. For example, the rejection set forth at section 8 beginning at page 3 of the FINAL Office action mailed June 9, 2005, indicates that the process described by Rye et al. produces isolated disseminated tumor cells, which are essentially unaltered from their original state, despite the inclusion in the process of a step by which the tumor cells are modified by means of an antibody prior to the step of filtering a cell suspension through a screen; see, in particular, pages 5 and 6 of the FINAL Office action, where this particular issue has been addressed in greater depth and detail. The fact that it is not inherently a property of the claimed process, per se, which does not comprise modifying tumor cells prior to passing fluids containing the cells through a screen, as opposed to the methods disclosed by the prior art of record, which do include such a step, to yield substantially unaltered disseminated tumor cells suggests that the disclosure at page 13, lines 25-32, cannot be regarded as inherent support for the subject matter that is now claimed.

Accordingly, it is believed that each and every argument set forth by Appellant has been carefully considered, though not found persuasive to overcome the stated grounds of rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(10) Response to Argument

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

George C. Elliott, Ph.D.
Director
Technology Center 1600

Conferees:

Larry R. Helms, Ph.D.,
Supervisory Patent Examiner
Art Unit 1643

LARRY R. HELMS, PH.D.
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